

## CRITERIA FOR PRIOR AUTHORIZATION

### Minimum Requirements Prior Authorization

<b>BILLING CODE TYPE</b>	For drug coverage and provider type information, see the <a href="#">KMAP Reference Codes webpage</a> .
<b>MANUAL GUIDELINES</b>	Prior authorization will be required for all current and future dose forms available. All medication-specific criteria, including drug-specific indication, age, and dose for each agent is defined in Table 1 below.

#### GENERAL CRITERIA FOR INITIAL PRIOR AUTHORIZATION: (must meet all of the following)

- Must be approved for the indication, age, and not exceed dosing limits listed in Table 1.
- Non-covered FDA-approved indications, if any, are also listed in Table 1. Per Section 1927 of the Social Security Act [42 USC § 1396r-8(d)(2)], as amended by P.L. 111-148 § 2502, certain drugs, or their medical use, may be excluded from coverage or otherwise restricted.
- For all agents listed, the preferred PDL drug, if applicable, which treats the PA indication, is required unless the patient meets the non-preferred PDL PA criteria.

#### CRITERIA FOR RENEWAL PRIOR AUTHORIZATION: (must meet all of the following)

- Must not exceed age and dosing limits listed in Table 1.

**LENGTH OF APPROVAL (INITIAL AND RENEWAL):** up to 12 months

#### FOR DRUGS THAT HAVE A CURRENT PA REQUIREMENT, BUT NOT FOR THE NEWLY APPROVED INDICATIONS, FOR OTHER FDA-APPROVED INDICATIONS, AND FOR CHANGES TO AGE REQUIREMENTS NOT LISTED WITHIN THE PA CRITERIA:

- **THE PA REQUEST WILL BE REVIEWED BASED UPON THE FOLLOWING PACKAGE INSERT INFORMATION: INDICATION, AGE, DOSE, AND ANY PRE-REQUISITE TREATMENT REQUIREMENTS FOR THAT INDICATION.**

**LENGTH OF APPROVAL (INITIAL AND RENEWAL):** up to 12 months

Table 1. FDA-approved indication, age, and dosing limits.<sup>1-4922</sup>

Medication	Indication(s)	Age	Dosing Limits	Non-covered FDA Indications
Amikacin (Arikayce®)	As part of combination therapy for refractory Mycobacterium avium complex (MAC) lung disease in patients who do not achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen.	≥ 18 years	590mg nebulized inhalation once per day.	N/A
Cannabidiol (Epidiolex®)	Treatment of seizures associated with Lennox-Gastaut syndrome (LGS).  Treatment of seizures associated with Dravet syndrome (DS).  <u>Treatment of seizures associated with Tuberous Sclerosis Complex (TSC).</u>	≥ <u>12</u> years	<u>LGS/DS:</u> 10mg/kg orally twice daily.  <u>TSC: 12.5mg/kg orally twice daily.</u>	N/A
Clobazam (Onfi®, Sympazan™)	Adjunctive treatment of seizures associated with LGS.	≥ 2 years	≤30kg: 20mg orally daily. >30kg: 40mg orally daily.	N/A
<del>Denosumab (Xgeva®)</del>	<del>Prevention of skeletal related events in multiple myeloma and in patients with bone metastases from solid tumors.</del>  <del>Treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity.</del>  <del>Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy.</del>	<del>≥18 years</del>  <del>≥13 years and skeletally mature for those with giant cell tumor of bone</del>	<del>120mg SQ every 4 weeks.</del>  <del>For giant cell tumor of bone or hypercalcemia of malignancy: Additional 120mg SQ on days 8 &amp; 15 are allowed in the first month.</del>	<del>N/A</del>
Dextromethorphan/quinnidine (Nuedexta®)	Treatment of pseudobulbar affect (PBA).	≥ 18 years	20mg/10mg orally every 12 hours.	N/A
Elexacaftor/tezacaftor/ivacaftor (Trikafta® <sup>TM</sup> )	Cystic fibrosis with ≥1 <i>F508del</i> mutation <u>or a mutation that is responsive based on in vitro data.</u>	≥ 12 years	2 combination tablets (100mg/50mg/75mg/tablet) orally in the morning and 1 ivacaftor 150mg tablet in the evening.	N/A

Medication	Indication(s)	Age	Dosing Limits	Non-covered FDA Indications
Eluxadoline (Viberzi <sup>®</sup> )	Irritable bowel syndrome with diarrhea (IBS-D).	≥ 18 years	100mg orally twice daily.	N/A
Fenfluramine (Fintepla <sup>®</sup> )	Treatment of seizures associated with Dravet Syndrome (DS)	≥ 2 years	0.35mg/kg orally twice daily or 26mg total daily dose.	N/A
Ivacaftor (Kalydeco <sup>®</sup> )	Cystic fibrosis with ≥1 CFTR gene mutation that is responsive to ivacaftor based on clinical and/or in vitro assay.	≥ <del>6</del> 4 months	<p><u>4 months to &lt; 6 months, ≥ 5 kg: 25mg packet orally every 12 hours.</u></p> <p><u>6 months to &lt; 6 years, 5kg to &lt; 7kg: 25mg packet orally every 12 hours</u></p> <p><u>6 months to &lt; 6 years, 7kg to &lt; 14kg: 50mg packet orally every 12 hours.</u></p> <p><u>6 months to &lt; 6 years, ≥ 14kg: 75mg packet orally every 12 hours.</u></p> <p><u>6 years and older: 150mg tablet orally every 12 hours.</u></p>	N/A
Lumacaftor/ivacaftor (Orkambi <sup>®</sup> )	Cystic fibrosis with homozygous <i>F508del</i> mutation.	≥ 2 years	<p>2-5 years, &lt;14kg: 100mg/125mg packet orally every 12 hours.</p> <p>2-5 years, ≥14kg: 150mg/188mg packet orally every 12 hours.</p> <p>6-11 years: 2 tablets (100mg/125mg/tablet) orally every 12 hours.</p>	N/A

Medication	Indication(s)	Age	Dosing Limits	Non-covered FDA Indications
			≥12 years: 2 tablets (200mg/125mg) orally every 12 hours.	
Mecasermin (Increlex®)	Growth failure in severe primary insulin-like growth factor-1 deficiency (Primary IGFD) or with growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH.	≥ 2 years	0.12mg/kg SQ twice daily.	N/A
Nintedanib (Ofev®)	Treatment of idiopathic pulmonary fibrosis.  Treatment of chronic fibrosing interstitial lung diseases with a progressive phenotype.  Slowing the rate of decline in pulmonary function in patients with systemic sclerosis-associated interstitial lung disease.	≥ 18 years	1 capsule (150mg) orally twice daily.	N/A
Ospemifene (Osphena®)	Treatment of moderate to severe dyspareunia or moderate to severe vaginal dryness due to menopause.	≥ 18 years and unable to become pregnant	60mg orally once daily.	N/A
Pirfenidone (Esbriet®)	Treatment of idiopathic pulmonary fibrosis	≥ 18 years	1 tablet (801mg) orally three times daily.	N/A
Romosozumab (Evenity®)	Treatment of osteoporosis in postmenopausal women at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or for patients who have failed or are intolerant to other available osteoporosis therapy.	≥ 18 years	Limit 12 monthly doses, with each dose limited to 210mg SQ each month	N/A
Rufinamide (Banzel®)	Adjunctive treatment of seizures associated with LGS.	≥ 1 year	45mg/kg/day up to 3,200mg orally per day.	N/A
<u>Somatropin (Serostim®)</u>	<u>Treatment of HIV patients with wasting or cachexia to increase lean body mass and body weight, and improve physical endurance.</u>	<u>&gt; 18 years</u>	<u>&gt;55kg: 6mg SQ daily.</u> <u>44-55kg: 5mg SQ daily.</u> <u>35-45kg: 4mg SQ daily.</u>	<u>N/A</u>

Medication	Indication(s)	Age	Dosing Limits	Non-covered FDA Indications
			<u>&lt;35kg: 0.1mg/kg SQ daily.</u>	
<u>Somatropin (Zorbtive®)</u>	<u>Treatment of short bowel syndrome in adult patients receiving specialized nutritional support.</u>	<u>&gt; 18 years</u>	<u>Lesser of 0.1mg/kg or 8mg SQ daily for 4 weeks.</u>	<u>N/A</u>
Solifenacin (Vesicare LS™)	Pediatric neurogenic detrusor overactivity	2-17 years	9-15 kg: 4 mg orally per day >15 to 30 kg: 5 mg orally per day >30 to 45 kg: 6 mg orally per day >45 to 60 kg: 7 mg orally per day >60 kg: 10 mg orally per day	N/A
Stiripentol (Diacomit®)	Treatment of seizures associated with Dravet syndrome taking clobazam.	≥ 2 years	3,000mg orally per day.	N/A
Telotristat ethyl (Xermelo™)	Carcinoid syndrome diarrhea in combination with somatostatin analog (SSA) therapy in those inadequately controlled by SSA therapy.	≥ 18 years	250mg orally three times daily.	N/A
Tezacaftor/ivacaftor (Symdeko®)	Cystic fibrosis with homozygous <i>F508del</i> mutation or ≥1 CFTR gene mutation that is responsive to tezacaftor/ivacaftor based on clinical and/or in vitro assay.	≥ 6 years	6 to <12 years, <30kg: 1 tablet (50mg/75mg) every morning and 1 ivacaftor tablet (75mg) orally every evening.  6 to <12 years, ≥30kg: 1 tablet (100mg/150mg) every morning and 1 ivacaftor 150mg tablet orally every evening.  ≥12 years: 1 tablet (100mg/150mg) every morning and 1 ivacaftor 150mg tablet orally every evening.	N/A

SQ = subcutaneously; LGS = Lennox-Gastaut Syndrome; DS = Dravet Syndrome; TSC = Tuberous sclerosis complex; IBS-D = Irritable bowel syndrome with diarrhea

References:

1. Arikayce (amikacin liposome inhalation suspension) [prescribing information]. Bridgewater, NJ: Insmed; ~~March~~ October 2020.
2. Epidiolex (cannabidiol) [prescribing information]. Carlsbad, CA: Greenwich Biosciences, Inc.; ~~Nov-2018~~ October 2020.
3. Onfi (clobazam) [prescribing information]. Deerfield, IL: Lundbeck; Jun 2018.
4. Sympazan (clobazam) [prescribing information]. Warren, NJ: Aquestive Therapeutics; Nov 2018.
- ~~5. Xgeva (denosumab) [package insert]. Thousand Oaks, CA: Amgen, Inc.; Feb 2020.~~
- ~~6.5.~~ 6.5. Nuedexta (dextromethorphan/quinidine) [package insert]. Aliso Viejo, CA: Avanir Pharmaceuticals, Inc. June 2019.
- ~~7.6.~~ 7.6. Trikafta (elexacaftor/tezacaftor/ivacaftor) [package insert]. Boston, MA: Vertex Pharmaceuticals Inc.; ~~October 2019~~ December 2020.
- ~~8.7.~~ 8.7. Viberzi (eluxadoline) [package insert]. Madison, NJ: Allergan USA, Inc.; June 202018.
- ~~9.8.~~ 9.8. Fintepla (fenfluramine) [package insert]. Emeryville, CA: Zogenix, Inc; June 2020.
- ~~10.9.~~ 10.9. Kalydeco (ivacaftor) [package insert]. Boston, MA: Vertex Pharmaceuticals Inc.; ~~April-2019~~ December 2020.
- ~~11.10.~~ 11.10. Orkambi (lumacaftor/ivacaftor) [package insert]. Boston, MA: Vertex Pharmaceuticals Inc.; July 2019.
- ~~12.11.~~ 12.11. Increlex (mecasermin) [package insert]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; Dec 2019.
- ~~13.12.~~ 13.12. Ofev (nintedanib) [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; ~~Mar~~ October 2020.
- ~~14.13.~~ 14.13. Osphena (ospemifene) [package insert]. Florham Park, NJ: Shionogi Inc.; Jan 2019.
- ~~15.14.~~ 15.14. Esbriet (pirfenidone) [package insert]. South San Francisco, CA: Genentech USA, Inc.; July 2019.
- ~~16.15.~~ 16.15. Evenity (romosozumab) [package insert]. Thousand Oaks, CA: Amgen Inc.; ~~December-2019~~ April 2020.
- ~~17.16.~~ 17.16. Banzel (rufinamide) [package insert]. Woodcliff Lake, NJ: Eisai, Inc.; ~~Nov-2019~~ April 2020.
- ~~18.17.~~ 18.17. Vesicare LS (solifenacin succinate) [prescribing information]. Northbrook, IL: Astellas Pharma US; May 2020.
- ~~19.18.~~ 19.18. Diacomit (stiripentol) [package insert]. Beauvais, France: Biocodex; Aug 2018.
- ~~20.19.~~ 20.19. Xermelo (telotristat ethyl) [package insert]. The Woodlands, TX: Lexicon Pharmaceuticals, Inc.; Feb 2017.
- ~~20.~~ 20. Symdeko (tezacaftor/ivacaftor) [package insert]. Boston, MA: Vertex Pharmaceuticals Inc.; ~~Dec-2019~~ December 2020.
- ~~21.~~ 21. Serostim (somatropin) [package insert]. Rockland, MA: EMD Serono, Inc.; June 2019.
- ~~21-22.~~ 21-22. Zorbtive (somatropin [package insert]. Rockland, MA: EMD Serono, Inc.; September 2019.

---

DRUG UTILIZATION REVIEW COMMITTEE CHAIR

---

PHARMACY PROGRAM MANAGER  
DIVISION OF HEALTH CARE FINANCE  
KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT

---

DATE

---

DATE